

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)
14 August 1998 (14.08.98)

International application No.
PCT/US98/01445

Applicant's or agent's file reference
L0461/7005WO

International filing date (day/month/year)
27 January 1998 (27.01.98)

Priority date (day/month/year)
27 January 1997 (27.01.97)

Applicant

LETHE, Bernard et al

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
22 July 1998 (22.07.98)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

J. Leitao

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference L0461/7005W0	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below	
International application No. PCT/US 98/ 01445	International filing date (day/month/year) 27/01/1998	(Earliest) Priority Date (day/month/year) 27/01/1997
Applicant LUDWIG INSTITUTE FOR CANCER RESEARCH et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☒ **Certain claims were found unsearchable** (see Box I).
2. ☐ **Unity of invention is lacking** (see Box II).
3. ☒ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
 - ☒ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ Transcribed by this Authority
4. With regard to the **title**,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
 - ☒ the text is approved as submitted by the applicant.
 - ☐ the text has been established, according to Rule 38 2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is
 - Figure No. 1
 - ☒ as suggested by the applicant
 - ☐ because the applicant failed to suggest a figure
 - ☐ because this figure better characterizes the invention
 - ☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/01445

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/12 C07K14/705 C07K16/18 C12Q1/68 A61K38/17
 //C12N15/11,A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C12N C07K C12Q A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	DATABASE EMBL - EMBEST1 Acc.No. AA634317, 31 October 1997 HILLIER, L. ET AL: "zu78e05.s1 Soares testis NHT Homo sapiens cDNA clone 744128 3'." XP002064910 see the whole document	1,7-15
P,X	CHEN, Y.-T. ET AL.: "A testicular antigen aberrantly expressed in human cancers detected by autologous antibody screening." PROC.NATL.ACAD.SCI.-USA, vol. 94, March 1997, pages 1914-1918, XP002064909 cited in the application	1,6, 17-20, 29, 33-35, 38-40
P,Y	see figure 3	41-51, 53-55

	--- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

14 May 1998

Date of mailing of the international search report

02.07.98

Name and mailing address of the ISA

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 NL - 2280 HV Rijswijk
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 Fax: (+31-70) 340-3016

Authorized officer

Smalt, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/01445

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 92 20356 A (LUDWIG INST CANCER RES) 26 November 1992 cited in the application See the whole document, particularly the claims, especially claims 77-92, 134 and 143 -----	41-51, 53-55

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/01445

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 43-48 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/01445

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9220356 A	26-11-1992	US 5342774 A	30-08-1994
		AU 664560 B	23-11-1995
		AU 2158392 A	30-12-1992
		CA 2109727 A	26-11-1992
		EP 0595838 A	11-05-1994
		FI 935174 A	22-11-1993
		JP 6511144 T	15-12-1994
		NO 934130 A	23-11-1993
		PT 100515 A	31-08-1993
		US 5541104 A	30-07-1996
		US 5612201 A	18-03-1997

PATENT COOPERATION TREATY

PCT

REC'D 15 APR 1999

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference L0461/7005WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US98/01445	International filing date (day/month/year) 27/01/1998	Priority date (day/month/year) 27/01/1997
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant LUDWIG INSTITUTE FOR CANCER RESEARCH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 22/07/1998	Date of completion of this report 13. 04. 99
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel (+49-89) 2399-0 Tx 523656 epmu d Fax (+49-89) 2399-4465	Authorized officer Huber, A Telephone No (+49-89) 2399 8173 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US98/01445

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-60 as originally filed

Claims, No.:

1-56 as originally filed

Drawings, sheets:

1/1 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US98/01445

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes	Claims	1-56
	No:	Claims	
Inventive step (IS)	Yes	Claims	1-56
	No:	Claims	
Industrial applicability (IA)	Yes	Claims	1-56 (see SECTION VII)
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US98/01445

SECTION V -----

1. The present application relates to LAGE-1 tumor associated nucleic acids and encoded polypeptides. They are useful in diagnostic and therapeutic applications for disorders associated with the expression of a LAGE-1 tumor associated polypeptide.
2. The preliminary examination report is established under the assumption that the priority has been validly claimed. If it later turns out that this is not the case, the following documents will have to be considered for the purpose of novelty and inventive step of the claimed subject-matter: Chen et al., PNAS, Vol. 94, pp. 1914-1918, March 1997; Hillier et al., EMBL Database Emest1, Accession No. AA634317, October 1997.

3. Reference is made to the following document:

D1: WO-A-92/20356

D1 discloses the identification and cloning of "MAGE" genes, which code for tumor rejection antigen precursors (TRAPs) and the peptides derived therefrom (TRAs). They are expressed by tumor cells and recognized by cytotoxic T-cells. Numerous other tumor rejection antigens (BAGE, RAGE, DAGE etc.) have also been disclosed in the prior art (cited in the application).

4. The present invention adds further tumor rejection antigens (LAGE-1a and LAGE-1b), which apparently do not show homology with any of the known TRAs. Tumor rejection antigens of the LAGE family have neither been disclosed nor could their existence have been derived from any of the cited documents in an obvious manner. Novelty and inventive step of the claimed subject-matter are therefore acknowledged (Art. 33(2) and (3) PCT).

SECTION VII -----

For the assessment of the present claims 43-48 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US98/01445

also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

SECTION VIII -----

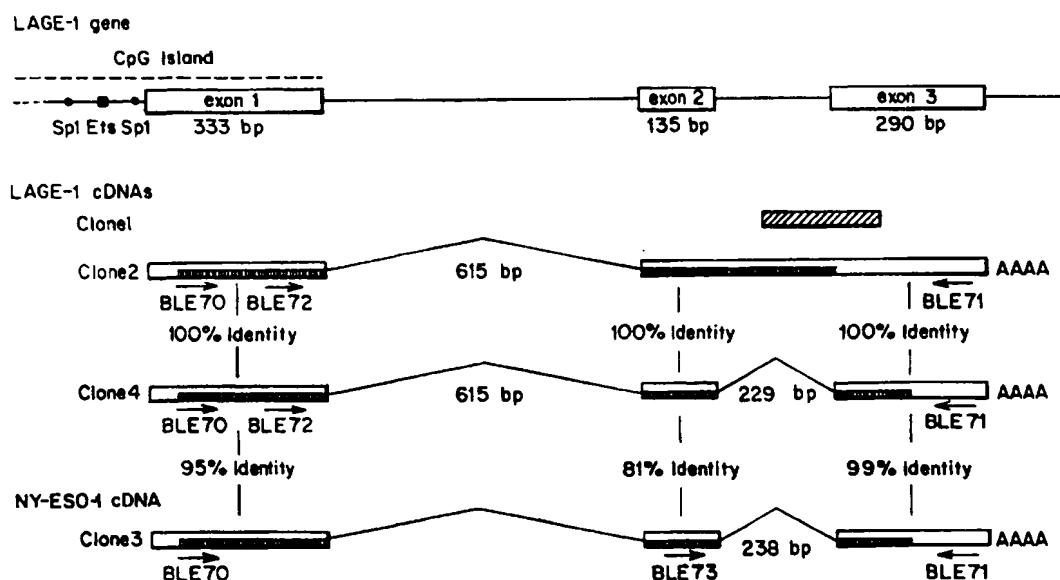
1. In independent Claims 45, 47, 49, 51 and 53-55 the subject-matter for which protection is sought is not sufficiently defined (Art. 6 PCT). The term "LAGE-1" is an internal and arbitrary designation for an apparently novel polypeptide and does not provide any technical teaching to the skilled person. Chemical compounds such as polypeptides or nucleic acids must be defined by unambiguous technical features such as their formula.
2. Claims 7-16 and 26-28 relate to "unique fragments" of the nucleic acids of SEQ ID Nos. 4 or 6 or the proteins of SEQ ID Nos. 5 or 7. First of all, the subject-matter of said claims is not sufficiently defined by all essential technical or functional features thereof (Art. 6 PCT). It should be noted that the claimed fragments do not need to be derived from a LAGE-1 encoding nucleic acid or from a LAGE-1 protein. Thus any fragment which has at least 12 nucleotides (or 9 amino acids) in common with the respective SEQ IDs falls under the scope of the claims, irrespective of the function of the molecule from which it is derived. The term "unique fragment" is unclear as such (unique with regard to what?) and cannot be used to adequately define the claimed matter or to distinguish it from prior art (a fragment of only 12 nucleotides does not seem to be specific for a nucleic acid coding for a LAGE-1 tumor associated antigen). Additionally, claims to fragments, which are not defined by clear structural or functional features, render the scope of the claims unclear and open to interpretation. It would also require undue burden from the person skilled in the art to determine whether a short nucleic acid or a peptide falls under the scope of the claim or not.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : C12N 15/12, C07K 14/705, 16/18, C12Q 1/68, A61K 38/17 // C12N 15/11, A61K 48/00	A1	(11) International Publication Number: WO 98/32855 (43) International Publication Date: 30 July 1998 (30.07.98)
(21) International Application Number: PCT/US98/01445 (22) International Filing Date: 27 January 1998 (27.01.98) (30) Priority Data: 08/791,495 27 January 1997 (27.01.97) US (71) Applicant (for all designated States except US): LUDWIG INSTITUTE FOR CANCER RESEARCH [CH/US]; 1345 Avenue of the Americas, New York, NY 10105 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): LETHE, Bernard [BE/BE]; Institute Ludwig pour la Recherche sur le Cancer, Avenue Hippocrate 74, UCL 7459, B-1200 Brussels (BE). LUCAS, Sophie [BE/BE]; Institute Ludwig pour la Recherche sur le Cancer, Avenue Hippocrate 74, UCL 7459, B-1200 Brussels (BE). DE SMET, Charles [BE/BE]; Institute Ludwig pour la Recherche sur le Cancer, Avenue Hippocrate 74, UCL 7459, B-1200 Brussels (BE). GODELAINE, Daniele [BE/BE]; Institute Ludwig pour la Recherche sur le Cancer, Avenue Hippocrate 74, UCL 7459, B-1200 Brussels (BE). BOON-FALLEUR, Thierry [BE/BE]; Institute Ludwig pour la Recherche sur le Cancer, Avenue Hippocrate 74, UCL 7459, B-1200 Brussels (BE).		(74) Agent: VAN AMSTERDAM, John, R.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US). (81) Designated States: AU, CA, CN, JP, KR, NZ, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: LAGE-1 TUMOR ASSOCIATED NUCLEIC ACIDS



(57) Abstract

The invention describes the LAGE-1 tumor associated gene, including fragments, allelic variants and splice variants thereof. Also included are polypeptides and fragments thereof encoded by such genes, and antibodies relating thereto. Methods and products also are provided for diagnosing and treating conditions characterized by expression of a LAGE-1 gene product.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/01445

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/12 C07K14/705 C07K16/18 C12Q1/68 A61K38/17
 //C12N15/11, A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C12N C07K C12Q A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	DATABASE EMBL - EMBEST1 Acc.No. AA634317, 31 October 1997 HILLIER, L. ET AL: "zu78e05.s1 Soares testis NHT Homo sapiens cDNA clone 744128 3'." XP002064910 see the whole document ---	1,7-15
P,X	CHEN, Y.-T. ET AL.: "A testicular antigen aberrantly expressed in human cancers detected by autologous antibody screening." PROC.NATL.ACAD.SCI.-USA, vol. 94, March 1997, pages 1914-1918, XP002064909 cited in the application	1,6, 17-20, 29, 33-35, 38-40
P,Y	see figure 3 ---	41-51, 53-55
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
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T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

14 May 1998

Date of mailing of the international search report

02.07.98

Name and mailing address of the ISA

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 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Smalt, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/01445

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 92 20356 A (LUDWIG INST CANCER RES) 26 November 1992 cited in the application See the whole document, particularly the claims, especially claims 77-92, 134 and 143 -----</p>	<p>41-51, 53-55</p>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/01445

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 43-48 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 98/01445

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9220356 A	26-11-1992	US 5342774 A	30-08-1994
		AU 664560 B	23-11-1995
		AU 2158392 A	30-12-1992
		CA 2109727 A	26-11-1992
		EP 0595838 A	11-05-1994
		FI 935174 A	22-11-1993
		JP 6511144 T	15-12-1994
		NO 934130 A	23-11-1993
		PT 100515 A	31-08-1993
		US 5541104 A	30-07-1996
		US 5612201 A	18-03-1997